

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

JOSEPH M. PRICE (SBN: 88201)
ERIN VERNERIS (SBN: 9335174)
FAEGRE & BENSON LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
Telephone: (612)766-7380
Facsimile: (612)766-1600
jprice@faegre.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION,
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

AMMIE JEAN FLEMING,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-01433-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company¹) ("Pharmacia") and
3 G.D. Searle LLC ("Searle") (collectively "Defendants") and file this Answer to Plaintiff's
4 Complaint ("Complaint"), and would respectfully show the Court as follows:

5
6 **I.**
7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
9 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
10 Defendants may seek leave to amend this Answer when discovery reveals the specific time
11 periods in which Plaintiff was prescribed and used Bextra®.

12 **II.**
13 **ORIGINAL ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants are without knowledge or information sufficient to form a belief as to
16 the truth of the allegations regarding Plaintiff's citizenship, and, therefore, deny the same.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 2. Defendants admit that Pfizer is a Delaware corporation with its principal place of
19 business in New York, and that it is registered to do business in the State of Minnesota.
20 Defendants admit that Pfizer may be served through its registered agent. Defendants admit that
21 Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and
22 Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time,

23 ¹ Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in
24 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the
25 laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia
26 Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was
27 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed
28 its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
agricultural business and does not and has not ever designed, produced, manufactured, sold,
resold, or distributed Bextra®. Given that Plaintiff alleges in the Complaint that Monsanto
Company was involved in distributing Bextra®, see PLAINTIFF'S COMPLAINT at ¶ 5, Defendants
assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the
allegations directed at Monsanto Company.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Pfizer marketed and co-promoted Bextra® in the United States, including Minnesota, to be
2 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
3 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding
4 "predecessors in interest" are vague and ambiguous. Defendants are therefore without
5 knowledge or information sufficient to form a belief as to the truth of such allegations, and,
6 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
7 Complaint.

8 3. Defendants admit that Searle is a Delaware limited liability company with its
9 principal place of business in Illinois, and that it is registered to do business in the State of
10 Minnesota. Defendants admit that Searle may be served through its registered agent.
11 Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in
12 April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during
13 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
14 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
15 healthcare providers who are by law authorized to prescribe drugs in accordance with their
16 approval by the FDA. Defendants deny the remaining allegations in this paragraph of the
17 Complaint.

18 4. Defendants admit that Pharmacia is a Delaware corporation with its principal
19 place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and
20 that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
21 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
22 Bextra® in the United States to be prescribed by healthcare providers who are by law authorized
23 to prescribe drugs in accordance with their approval by the FDA. Defendants state that
24 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants
25 are therefore without knowledge or information sufficient to form a belief as to the truth of such
26 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this
27 paragraph of the Complaint.

28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 5. Defendants admit that in 1933 an entity known as Monsanto Company (“1933
2 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
3 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to
4 Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was
5 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed
6 its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged in the
7 agricultural business and does not and has not ever manufactured, marketed, sold, or distributed
8 Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia.
9 As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed
10 Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter.
11 Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state
12 that the response to this paragraph of the Complaint regarding Monsanto is incorporated by
13 reference into Defendants’ responses to each and every paragraph of the Complaint referring to
14 Monsanto and/or Defendants.

15 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
16 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers
17 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
18 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged
19 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the
20 United States to be prescribed by healthcare providers who are by law authorized to prescribe
21 drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired
22 Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became
23 subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the
24 Complaint.

25 7. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
26 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers
27 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
28 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the
2 United States to be prescribed by healthcare providers who are by law authorized to prescribe
3 drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is
4 safe and effective when used in accordance with its FDA-approved prescribing information.
5 Defendants state that the potential effects of Bextra® were and are adequately described in its
6 FDA-approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 8. Defendants state that the allegations in this paragraph of the Complaint regarding
10 “predecessors in interest” are vague and ambiguous. Defendants are therefore without
11 knowledge or information sufficient to form a belief as to the truth of such allegations, and,
12 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
13 Complaint.

14 9. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of
15 Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 10. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of
17 Minnesota. Defendants are without knowledge sufficient to form a belief as to the allegations in
18 this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the
19 same. However, Defendants admit that Plaintiff claims the amount in controversy satisfies the
20 jurisdictional amount of this Court. Defendants deny the remaining allegations in this paragraph
21 of the Complaint.

22 **Response to Factual Allegations**

23 11. Defendants are without knowledge or information sufficient to form a belief as to
24 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 12. Defendants are without knowledge or information sufficient to form a belief as to
28 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 deny that Bextra® caused Plaintiff injury or damages and deny the remaining allegations in this
4 paragraph of the Complaint.

5 13. Defendants are without knowledge or information sufficient to form a belief as to
6 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Bextra® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra®
12 caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the
13 Complaint.

14 14. Defendants are without knowledge or information sufficient to form a belief as to
15 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Bextra®, and, therefore, deny the same. Defendants state that, in the ordinary case, Bextra® was
17 expected to reach users and consumers without substantial change from the time of sale.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 15. Defendants are without knowledge or information sufficient to form a belief as to
20 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Bextra® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to
28 as non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that the allegations in

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 this paragraph of the Complaint regarding aspirin, naproxen and ibuprofen are not directed
2 toward Defendants, and, therefore, no response is required. To the extent a response is deemed
3 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
4 this paragraph of the Complaint regarding aspirin, naproxen and ibuprofen. Defendants
5 therefore lack knowledge or information sufficient to form a belief as to the truth of such
6 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this
7 paragraph of the Complaint.

8 17. The allegations in this paragraph of the Complaint are not directed toward
9 Defendants, and, therefore, no response is required. To the extent a response is deemed
10 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
11 this paragraph of the Complaint. Defendants therefore lack knowledge or information
12 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

13 18. The allegations in this paragraph of the Complaint are not directed toward
14 Defendants, and, therefore, no response is required. To the extent a response is deemed
15 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
16 this paragraph of the Complaint. Defendants therefore lack knowledge or information
17 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

18 19. The allegations in this paragraph of the Complaint are not directed toward
19 Defendants, and, therefore, no response is required. To the extent a response is deemed
20 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
21 this paragraph of the Complaint. Defendants therefore lack knowledge or information
22 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

23 20. The allegations in this paragraph of the Complaint are not directed toward
24 Defendants, and, therefore, no response is required. To the extent a response is deemed
25 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
26 this paragraph of the Complaint. Defendants therefore lack knowledge or information
27 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.
28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 21. Plaintiff fails to provide the proper context for the allegations in this paragraph
2 of the Complaint. Defendants lack knowledge or information sufficient to form a belief as to
3 the truth of such allegations, and, therefore, deny the same.

4 22. Defendants state that Plaintiff's allegations regarding "predecessors in interest"
5 are vague and ambiguous. Defendants are therefore without knowledge or information to form
6 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any
7 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8 23. Plaintiff does not allege having used Celebrex® in this Complaint.
9 Nevertheless, Defendants admit that Celebrex® was launched in the United States in February
10 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants admit that, during certain periods
12 of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
13 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
14 with their approval by the FDA. Defendants admit that, during certain periods of time,
15 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
16 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
17 providers who are by law authorized to prescribe drugs in accordance with their approval by the
18 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
19 directed toward Defendants, and, therefore, no response is required. To the extent a response is
20 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
21 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
22 therefore lack knowledge or information sufficient to form a belief as to the truth of such
23 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this
24 paragraph of the Complaint.

25 24. Defendants admit that the New Drug Application for Bextra® was filed with the
26 FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by
27 the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of
28 osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 dysmenorrhea. Defendants state that Plaintiff's allegations regarding "predecessors in interest"
2 are vague and ambiguous. Defendants are therefore without knowledge or information to form
3 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the
4 remaining allegations in this paragraph of the Complaint.

5 25. Defendants admit that Bextra® was approved by the FDA on November 16,
6 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
7 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
8 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
9 the remaining allegations in this paragraph of the Complaint.

10 26. Defendants admit, as indicated in the package insert approved by the FDA, that
11 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
12 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
13 the remaining allegations in this paragraph of the Complaint.

14 27. Defendants admit, as indicated in the package insert approved by the FDA, that
15 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
16 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
17 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
18 prescribing information. Defendants state that the potential effects of Bextra® were and are
19 adequately described in its FDA-approved prescribing information, which at all times was
20 adequate and comported with applicable standards of care and law. Defendants deny the
21 remaining allegations in this paragraph of the Complaint.

22 28. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
23 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
24 providers who are by law authorized to prescribe drugs in accordance with their approval by the
25 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
26 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
27 in the United States to be prescribed by healthcare providers who are by law authorized to
28 prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 allegations regarding “predecessors in interest” are vague and ambiguous. Defendants are
2 therefore without knowledge or information to form a belief as to the truth of such allegations,
3 and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective
4 when used in accordance with its FDA-approved prescribing information. Defendants state that
5 the potential effects of Bextra® were and are adequately described in its FDA-approved
6 prescribing information, which at all times was adequate and comported with applicable
7 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
8 allegations in this paragraph of the Complaint.

9 29. Defendants state that the referenced article speaks for itself and respectfully refer
10 the Court to the article for its actual language and text. Any attempt to characterize the article
11 is denied. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
13 this paragraph of the Complaint.

14 30. The allegations in this paragraph of the Complaint are not directed towards
15 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,
16 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
17 the article for its actual language and text. Any attempt to characterize the article is denied.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 31. Defendants admit that the New Drug Application for Bextra® was filed with the
20 FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on
21 November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in
22 this paragraph of the Complaint.

23 32. Defendants state that Bextra® was and is safe and effective when used in
24 accordance with its FDA-approved prescribing information. Defendants state that the potential
25 effects of Bextra® were and are adequately described in its FDA-approved prescribing
26 information, which at all times was adequate and comported with applicable standards of care
27 and law. Defendants deny the allegations in this paragraph of the Complaint.

28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for
2 itself and respectfully refer the Court to the Talk Paper for its actual language and text. Any
3 attempt to characterize the Talk Paper is denied. Defendants deny the remaining allegations in
4 this paragraph of the Complaint.

5 34. Defendants state that the referenced article speaks for itself and respectfully refer
6 the Court to the article for its actual language and text. Any attempt to characterize the article
7 is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 35. Plaintiff fails to provide the proper context for the allegations concerning the
9 “post-drug approval meta-analysis study” in this paragraph of the Complaint. Defendants are
10 without sufficient information to confirm or deny such allegations, and, therefore, deny the
11 same. Defendants state that the referenced study speaks for itself and respectfully refer the
12 Court to the study for its actual language and text. Any attempt to characterize the study is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 36. The allegations in this paragraph of the Complaint are not directed towards
15 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,
16 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
17 the article for its actual language and text. Any attempt to characterize the article is denied.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 37. The allegations in this paragraph of the Complaint are not directed towards
20 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,
21 Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety
22 and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants
23 state that the referenced testimony speaks for itself and respectfully refer the Court to the
24 testimony for its actual language and text. Any attempt to characterize the testimony is denied.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 38. Defendants state that Bextra® was and is safe and effective when used in
27 accordance with its FDA-approved prescribing information. Defendants state that the potential
28 effects of Bextra® were and are adequately described in its FDA-approved prescribing

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 information, which at all times was adequate and comported with applicable standards of care
2 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
3 paragraph of the Complaint.

4 39. Defendants state that the referenced Alert for Healthcare Professionals speaks
5 for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual
6 language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 40. Defendants state that the referenced Alert for Healthcare Professionals speaks
9 for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual
10 language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 41. Defendants state that Bextra® was and is safe and effective when used in
13 accordance with its FDA-approved prescribing information. Defendants deny the allegations in
14 this paragraph of the Complaint.

15 42. Defendants state that the referenced article speaks for itself and respectfully refer
16 the Court to the article for its actual language and text. Any attempt to characterize the article
17 is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 43. The allegations in this paragraph of the Complaint are not directed towards
20 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,
21 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
22 the article for its actual language and text. Any attempt to characterize the article is denied.
23 Defendants deny the remaining allegations in this paragraph of the Complaint.

24 44. Defendants state that Bextra® was and is safe and effective when used in
25 accordance with its FDA-approved prescribing information. Defendants state that the potential
26 effects of Bextra® were and are adequately described in its FDA-approved prescribing
27 information, which was at all times adequate and comported with applicable standards of care
28 and law. Defendants deny the allegations in this paragraph of the Complaint.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 45. Defendants state that Bextra® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants state that the potential
3 effects of Bextra® were and are adequately described in its FDA-approved prescribing
4 information, which was at all times adequate and comported with applicable standards of care
5 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the
6 remaining allegations in this paragraph of the Complaint.

7 46. Defendants state that Bextra® was and is safe and effective when used in
8 accordance with its FDA-approved prescribing information. Defendants state that the potential
9 effects of Bextra® were and are adequately described in its FDA-approved prescribing
10 information, which was at all times adequate and comported with applicable standards of care
11 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
12 paragraph of the Complaint.

13 47. Defendants deny the allegations in this paragraph of the Complaint.

14 48. Defendants are without knowledge or information sufficient to form a belief as
15 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
16 used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of
17 time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be
18 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
19 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®
20 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
21 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
22 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
23 state that Bextra® was and is safe and effective when used in accordance with its FDA-
24 approved prescribing information. Defendants state that the potential effects of Bextra® were
25 and are adequately described in its FDA-approved prescribing information, which was at all
26 times adequate and comported with applicable standards of care and law. Defendants deny any
27 wrongful conduct and deny the allegations in this paragraph of the Complaint.

28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
2 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
3 providers who are by law authorized to prescribe drugs in accordance with their approval by the
4 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
5 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
6 in the United States to be prescribed by healthcare providers who are by law authorized to
7 prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra®
8 was and is safe and effective when used in accordance with its FDA-approved prescribing
9 information. Defendants state that the potential effects of Bextra® were and are adequately
10 described in its FDA-approved prescribing information, which was at all times adequate and
11 comported with applicable standards of care and law. Defendants deny the remaining
12 allegations in this paragraph of the Complaint.

13 50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
14 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
15 providers who are by law authorized to prescribe drugs in accordance with their approval by the
16 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
18 in the United States to be prescribed by healthcare providers who are by law authorized to
19 prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated
20 in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the
21 signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment
22 of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when
23 used in accordance with its FDA-approved prescribing information. Defendants state that the
24 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing
25 information, which was at all times adequate and comported with applicable standards of care
26 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
27 paragraph of the Complaint.
28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 51. Defendants state that Bextra® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants state that the potential
3 effects of Bextra® were and are adequately described in its FDA-approved prescribing
4 information, which at all times was adequate and comported with applicable standards of care
5 and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
6 vague and ambiguous. Defendants are therefore without knowledge or information to form a
7 belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any
8 wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of
9 the Complaint.

10 52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
11 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
12 providers who are by law authorized to prescribe drugs in accordance with their approval by the
13 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
14 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
15 in the United States to be prescribed by healthcare providers who are by law authorized to
16 prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra®
17 was and is safe and effective when used in accordance with its FDA-approved prescribing
18 information. Defendants state that the potential effects of Bextra® were and are adequately
19 described in its FDA-approved prescribing information, which was at all times adequate and
20 comported with applicable standards of care and law. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 53. Defendants state that Bextra® was and is safe and effective when used in
23 accordance with its FDA-approved prescribing information. Defendants state that the potential
24 effects of Bextra® were and are adequately described in its FDA-approved prescribing
25 information, which at all times was adequate and comported with applicable standards of care
26 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 54. Defendants state that Bextra® was and is safe and effective when used in
28 accordance with its FDA-approved prescribing information. Defendants state that the potential

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 effects of Bextra® were and are adequately described in its FDA-approved prescribing
2 information, which was at all times adequate and comported with applicable standards of care
3 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
4 paragraph of the Complaint.

5 55. Defendants state that Bextra® was and is safe and effective when used in
6 accordance with its FDA-approved prescribing information. Defendants state that the potential
7 effects of Bextra® were and are adequately described in its FDA-approved prescribing
8 information, which was at all times adequate and comported with applicable standards of care
9 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
10 paragraph of the Complaint.

11 56. Defendants deny the allegations in this paragraph of the Complaint.

12 57. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S.
13 market as of April 7, 2005. Defendants state that Bextra® was and is safe and effective when
14 used in accordance with its FDA-approved prescribing information. Defendants deny any
15 wrongful conduct and deny the remaining allegations contained in this paragraph of the
16 Complaint.

17 58. Defendants state that Bextra® was and is safe and effective when used in
18 accordance with its FDA-approved prescribing information. Defendants state that the potential
19 effects of Bextra® were and are adequately described in its FDA-approved prescribing
20 information, which was at all times adequate and comported with applicable standards of care
21 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the
22 remaining allegations in this paragraph of the Complaint.

23 59. Defendants state that Bextra® was and is safe and effective when used in
24 accordance with its FDA-approved prescribing information. Defendants state that the potential
25 effects of Bextra® were and are adequately described in its FDA-approved prescribing
26 information, which was at all times adequate and comported with applicable standards of care
27 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 60. Defendants deny any wrongful conduct and deny the remaining allegations in
2 this paragraph of the Complaint.

3 61. Defendants are without knowledge or information sufficient to form a belief as
4 to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff
5 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
6 and effective when used in accordance with its FDA-approved prescribing information.
7 Defendants state that the potential effects of Bextra® were and are adequately described in its
8 FDA-approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 62. Defendants are without knowledge or information sufficient to form a belief as
12 to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff
13 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
14 and effective when used in accordance with its FDA-approved prescribing information.
15 Defendants state that the potential effects of Bextra® were and are adequately described in its
16 FDA-approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
20 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
22 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
23 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
24 in the United States to be prescribed by healthcare providers who are by law authorized to
25 prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated
26 in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the
27 signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment
28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 of primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining
2 allegations in this paragraph of the Complaint.

3 64. Defendants are without knowledge or information sufficient to form a belief as
4 to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff
5 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
6 and effective when used in accordance with its FDA-approved prescribing information.
7 Defendants state that the potential effects of Bextra® were and are adequately described in its
8 FDA-approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
10 Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the
11 Complaint.

12 65. Defendants state that Bextra® was and is safe and effective when used in
13 accordance with its FDA-approved prescribing information. Defendants state that the potential
14 effects of Bextra® were and are adequately described in its FDA-approved prescribing
15 information, which was at all times adequate and comported with applicable standards of care
16 and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
17 vague and ambiguous. Defendants are therefore without knowledge or information to form a
18 belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any
19 wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or
20 damages, and deny the remaining allegations in this paragraph of the Complaint.

21 **Response to First Cause of Action: Negligence**

22 66. Defendants incorporate by reference their responses to each paragraph of
23 Plaintiff's Complaint as if fully set forth herein.

24 67. Defendants state that this paragraph of the Complaint contains legal contentions
25 to which no response is deemed required. To the extent a response is deemed required,
26 Defendants admit that they had duties as are imposed by law but deny having breached such
27 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 68. Defendants state that this paragraph of the Complaint contains legal contentions
5 to which no response is deemed required. To the extent a response is deemed required,
6 Defendants admit that they had duties as are imposed by law but deny having breached such
7 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 69. Defendants state that Bextra® was and is safe and effective when used in
13 accordance with its FDA-approved prescribing information. Defendants state that the potential
14 effects of Bextra® were and are adequately described in its FDA-approved prescribing
15 information, which was at all times adequate and comported with applicable standards of care
16 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint, including all subparts.

18 70. Defendants are without knowledge or information sufficient to form a belief as
19 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
20 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
21 and effective when used in accordance with its FDA-approved prescribing information.
22 Defendants state that the potential effects of Bextra® were and are adequately described in its
23 FDA-approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
25 Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the
26 Complaint.

27 71. Defendants state that Bextra® was and is safe and effective when used in
28 accordance with its FDA-approved prescribing information. Defendants state that the potential

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 effects of Bextra® were and are adequately described in its FDA-approved prescribing
2 information, which was at all times adequate and comported with applicable standards of care
3 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
4 paragraph of the Complaint.

5 72. Defendants are without knowledge or information sufficient to form a belief as
6 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
7 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
8 and effective when used in accordance with its FDA-approved prescribing information.
9 Defendants state that the potential effects of Bextra® were and are adequately described in its
10 FDA-approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
14 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

15 74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
16 injury or damages and deny the remaining allegations in this paragraph of the Complaint.

17 Answering the unnumbered paragraph following Paragraph 74 of the Complaint,
18 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages,
and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

19 75. Defendants incorporate by reference their responses to each paragraph of
20 Plaintiff's Complaint as if fully set forth herein.

21 76. Defendants are without knowledge or information sufficient to form a belief as
22 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
23 used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of
24 time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be
25 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
26 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®
27 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
28 and distributed Bextra® in the United States to be prescribed by healthcare providers who are

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that Bextra® was expected to reach consumers without substantial change in the
3 condition from the time of sale. Defendants deny the remaining allegations in this paragraph of
4 the Complaint.

5 77. Defendants state that Bextra® was and is safe and effective when used in
6 accordance with its FDA-approved prescribing information. Defendants state that the potential
7 effects of Bextra® were and are adequately described in its FDA-approved prescribing
8 information, which was at all times adequate and comported with applicable standards of care
9 and law. Defendants deny the allegations in this paragraph of the Complaint.

10 78. Defendants state that Bextra® was and is safe and effective when used in
11 accordance with its FDA-approved prescribing information. Defendants state that the potential
12 effects of Bextra® were and are adequately described in its FDA-approved prescribing
13 information, which was at all times adequate and comported with applicable standards of care
14 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or
15 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

16 79. Defendants state that Bextra® was and is safe and effective when used in
17 accordance with its FDA-approved prescribing information. Defendants state that the potential
18 effects of Bextra® were and are adequately described in its FDA-approved prescribing
19 information, which was at all times adequate and comported with applicable standards of care
20 and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably
21 dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all
22 subparts.

23 80. Defendants are without knowledge or information sufficient to form a belief as
24 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
25 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
26 and effective when used in accordance with its FDA-approved prescribing information.
27 Defendants state that the potential effects of Bextra® were and are adequately described in its
28 FDA-approved prescribing information, which was at all times adequate and comported with

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
2 Bextra® is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the
3 remaining allegations in this paragraph of the Complaint.

4 81. Defendants state that Bextra® was and is safe and effective when used in
5 accordance with its FDA-approved prescribing information. Defendants state that the potential
6 effects of Bextra® were and are adequately described in its FDA-approved prescribing
7 information, which was at all times adequate and comported with applicable standards of care
8 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the
9 remaining allegations in this paragraph of the Complaint.

10 82. Defendants are without knowledge or information sufficient to form a belief as
11 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
12 used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of
13 time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be
14 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
15 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®
16 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
17 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
18 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
19 state that Bextra® was and is safe and effective when used in accordance with its FDA-
20 approved prescribing information. Defendants state that the potential effects of Bextra® were
21 and are adequately described in its FDA-approved prescribing information, which was at all
22 times adequate and comported with applicable standards of care and law. Defendants deny any
23 wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or
24 damages, and deny the remaining allegations in this paragraph of the Complaint.

25 83. Defendants state that Bextra® was and is safe and effective when used in
26 accordance with its FDA-approved prescribing information. Defendants state that the potential
27 effects of Bextra® were and are adequately described in its FDA-approved prescribing
28 information, which was at all times adequate and comported with applicable standards of care

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
2 paragraph of the Complaint.

3 84. Defendants are without knowledge or information sufficient to form a belief as
4 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
5 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
6 and effective when used in accordance with its FDA-approved prescribing information.
7 Defendants state that the potential effects of Bextra® were and are adequately described in its
8 FDA-approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 85. Defendants state that Bextra® was and is safe and effective when used in
12 accordance with its FDA-approved prescribing information. Defendants deny any wrongful
13 conduct and deny the remaining allegations in this paragraph of the Complaint.

14 86. Defendants state that Bextra® was and is safe and effective when used in
15 accordance with its FDA-approved prescribing information. Defendants state that the potential
16 effects of Bextra® were and are adequately described in its FDA-approved prescribing
17 information, which was at all times adequate and comported with applicable standards of care
18 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the
19 remaining allegations in this paragraph of the Complaint.

20 87. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
21 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

22 88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
23 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

24 89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
25 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

26 **Response to Third Cause of Action: Breach of Express Warranty**

27 90. Defendants incorporate by reference their responses to each paragraph of
28 Plaintiff's Complaint as if fully set forth herein.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 91. Defendants are without knowledge or information sufficient to form a belief as
2 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
3 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
4 and effective when used in accordance with its FDA-approved prescribing information.
5 Defendants state that the potential effects of Bextra® were and are adequately described in its
6 FDA-approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants admit that they provided FDA-approved
8 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 92. Defendants are without knowledge or information sufficient to form a belief as
11 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
12 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
13 and effective when used in accordance with its FDA-approved prescribing information.
14 Defendants state that the potential effects of Bextra® were and are adequately described in its
15 FDA-approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants admit that they provided FDA-approved
17 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
18 paragraph of the Complaint, including all subparts.

19 93. Defendants deny the allegations in this paragraph of the Complaint.

20 94. Defendants state that Bextra® was and is safe and effective when used in
21 accordance with its FDA-approved prescribing information. Defendants state that the potential
22 effects of Bextra® were and are adequately described in its FDA-approved prescribing
23 information, which was at all times adequate and comported with applicable standards of care
24 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 95. Defendants state that Bextra® was and is safe and effective when used in
26 accordance with its FDA-approved prescribing information. Defendants state that the potential
27 effects of Bextra® were and are adequately described in its FDA-approved prescribing
28 information, which was at all times adequate and comported with applicable standards of care

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 and law. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
2 the Complaint.

3 96. Defendants are without knowledge or information sufficient to form a belief as
4 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
5 used Bextra®, and, therefore, deny the same. Defendants admit that they provided FDA-
6 approved prescribing information regarding Bextra®. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 97. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
9 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

10 98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
11 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

12 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
13 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

14 **Response to Fourth Cause of Action: Breach of Implied Warranty**

15 100. Defendants incorporate by reference their responses to each paragraph of
16 Plaintiff's Complaint as if fully set forth herein.

17 101. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
18 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
19 providers who are by law authorized to prescribe drugs in accordance with their approval by the
20 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
22 in the United States to be prescribed by healthcare providers who are by law authorized to
23 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
24 allegations in this paragraph of the Complaint.

25 102. Defendants admit that they provided FDA-approved prescribing information
26 regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the
27 Complaint.
28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 103. Defendants state that Bextra® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants deny any wrongful
3 conduct and deny the remaining allegations in this paragraph of the Complaint.

4 104. Defendants state that Bextra® was and is safe and effective when used in
5 accordance with its FDA-approved prescribing information. Defendants state that the potential
6 effects of Bextra® were and are adequately described in its FDA-approved prescribing
7 information, which was at all times adequate and comported with applicable standards of care
8 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
9 paragraph of the Complaint.

10 105. Defendants are without knowledge or information sufficient to form a belief as
11 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
12 used Bextra®, and, therefore, deny the same. Defendants admit, as indicated in the package
13 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and
14 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
15 primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the
16 Complaint.

17 106. Defendants state that this paragraph of the Complaint contains legal contentions
18 to which no response is deemed required. To the extent a response is deemed required,
19 Defendants are without knowledge or information sufficient to form a belief as to the truth of
20 the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
21 and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective
22 when used in accordance with its FDA-approved prescribing information. Defendants state that
23 the potential effects of Bextra® were and are adequately described in its FDA-approved
24 prescribing information, which was at all times adequate and comported with applicable
25 standards of care and law. Defendants admit that they provided FDA-approved prescribing
26 information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of
27 the Complaint.

28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 107. Defendants are without knowledge or information sufficient to form a belief as
2 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
3 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was expected to
4 reach consumers without substantial change in the condition from the time of sale. Defendants
5 deny the remaining allegations in this paragraph of the Complaint.

6 108. Defendants are without knowledge or information sufficient to form a belief as
7 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
8 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
9 and effective when used in accordance with its FDA-approved prescribing information.
10 Defendants state that the potential effects of Bextra® were and are adequately described in its
11 FDA-approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
13 remaining allegations in this paragraph of the Complaint.

14 109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
15 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

16 110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
17 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

18 111. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
19 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

20 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

21 112. Defendants incorporate by reference their responses to each paragraph of
22 Plaintiff's Complaint as if fully set forth herein.

23 113. Defendants state that this paragraph of the Complaint contains legal contentions
24 to which no response is deemed required. To the extent a response is deemed required,
25 Defendants admit that they had duties as are imposed by law but deny having breached such
26 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 114. Defendants state that Bextra® was and is safe and effective when used in
4 accordance with its FDA-approved prescribing information. Defendants state that the potential
5 effects of Bextra® were and are adequately described in its FDA-approved prescribing
6 information, which was at all times adequate and comported with applicable standards of care
7 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
8 paragraph of the Complaint, including all subparts.

9 115. Defendants state that Bextra® was and is safe and effective when used in
10 accordance with its FDA-approved prescribing information. Defendants state that the potential
11 effects of Bextra® were and are adequately described in its FDA-approved prescribing
12 information, which was at all times adequate and comported with applicable standards of care
13 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
14 paragraph of the Complaint.

15 116. Defendants state that Bextra® was and is safe and effective when used in
16 accordance with its FDA-approved prescribing information. Defendants state that the potential
17 effects of Bextra® were and are adequately described in its FDA-approved prescribing
18 information, which was at all times adequate and comported with applicable standards of care
19 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or
20 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

21 117. Defendants state that Bextra® was and is safe and effective when used in
22 accordance with its FDA-approved prescribing information. Defendants state that the potential
23 effects of Bextra® were and are adequately described in its FDA-approved prescribing
24 information, which was at all times adequate and comported with applicable standards of care
25 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 118. Defendants deny any wrongful conduct and deny the remaining allegations in
28 this paragraph of the Complaint.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 119. Defendants are without knowledge or information sufficient to form a belief as
2 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
3 used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny
4 the remaining allegations in this paragraph of the Complaint.

5 120. Defendants are without knowledge or information sufficient to form a belief as
6 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
7 used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny
8 the remaining allegations in this paragraph of the Complaint.

9 121. Defendants are without knowledge or information sufficient to form a belief as
10 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
11 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
12 and effective when used in accordance with its FDA-approved prescribing information.
13 Defendants state that the potential effects of Bextra® were and are adequately described in its
14 FDA-approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 122. Defendants deny any wrongful conduct and deny the remaining allegations in
18 this paragraph of the Complaint.

19 123. Defendants are without knowledge or information sufficient to form a belief as
20 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
21 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
22 and effective when used in accordance with its FDA-approved prescribing information.
23 Defendants state that the potential effects of Bextra® were and are adequately described in its
24 FDA-approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
28 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

1 125. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
2 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

3 126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff
4 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Sixth Cause of Action: Unjust Enrichment**

6 127. Defendants incorporate by reference their responses to each paragraph of
7 Plaintiff's Complaint as if fully set forth herein.

8 128. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
9 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
10 providers who are by law authorized to prescribe drugs in accordance with their approval by the
11 FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and
12 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
13 in the United States to be prescribed by healthcare providers who are by law authorized to
14 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 129. Defendants are without knowledge or information sufficient to form a belief as
17 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
18 used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this
19 paragraph of the Complaint.

20 130. Defendants are without knowledge or information sufficient to form a belief as
21 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
22 used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this
23 paragraph of the Complaint.

24 131. Defendants are without knowledge or information sufficient to form a belief as
25 to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff
26 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe
27 and effective when used in accordance with its FDA-approved prescribing information.
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,” Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

III. GENERAL DENIAL

Defendants deny the allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

IV. AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants’ labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling,

1 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or
2 persons acting on its behalf after the product left the control of Defendants.

3 **Seventeenth Defense**

4 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
5 Defendants.

6 **Eighteenth Defense**

7 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
8 conditions unrelated to Bextra®.

9 **Nineteenth Defense**

10 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the
11 doctrine of assumption of the risk bars or diminishes any recovery.

12 **Twentieth Defense**

13 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
14 preempted in accordance with the Supremacy Clause of the United States Constitution and by
15 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

16 **Twenty-first Defense**

17 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
18 the subject pharmaceutical product at issue was subject to and received pre-market approval by
19 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

20 **Twenty-second Defense**

21 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
22 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
23 and Plaintiff's causes of action are preempted.

24 **Twenty-third Defense**

25 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
26 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
27 issue under applicable federal laws, regulations, and rules.

28

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the State of Minnesota, and the Constitution of the State of Alabama, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Alabama law, including, but not limited to, Minn. Stat. § 549.191 (2006).

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota and Alabama. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug, & Cosmetic Act

(“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff’s claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff’s claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff’s misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff’s claims.

V.

JURY DEMAND

Defendants hereby demand a trial by jury.

VI.

PRAYER

WHEREFORE, Defendants pray that Plaintiff takes nothing by this suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which Defendants may be justly entitled.

Dated: May 19, 2008.

GORDON & REES LLP

By _____/s/_____

Stuart M. Gordon
275 Battery Street, 20th Floor
San Francisco, CA 94111
T (415)986-5900
F (415)986-8054

Gordon & Rees LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Dated: May 19, 2008

FAEGRE & BENSON LLP

By _____/s/_____
Joseph M. Price
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
T (612)766-7000
F (612)766-1600
*Attorneys for Defendants Pfizer Inc.,
Pharmacia Corporation, and G.D. Searle LLC*

Pursuant to Federal Rule of Civil Procedure 7.1, Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") submit this their Corporate Disclosure Statement. Defendants Pfizer, Pharmacia and Searle state:

1. Defendant Pfizer Inc. does not have any parent corporations, and no publicly traded company owns 10% or more of Pfizer Inc.'s stock.
2. Defendant Pharmacia Corporation is a wholly-owned subsidiary of Defendant Pfizer Inc.
3. Defendant G.D. Searle LLC is a limited liability company whose sole member is Pharmacia & Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation.

May 19, 2008

GORDON & REES LLP

By: /s/
 Stuart M. Gordon
 sgordon@gordonrees.com
 Embarcadero Center West
 275 Battery Street, 20th Floor
 San Francisco, CA 94111
 Telephone: (415) 986-5900
 Fax: (415) 986-8054

May 19, 2008

FAEGRE & BENSON LLP

By: /s/
 Joseph M. Price
jprice@faegre.com
 2200 Wells Fargo Center
 90 South Seventh Street
 MINNEAPOLIS, MN 55402-3901
 Telephone: (612)766-7000
 Fax: (612) 766-1600

Attorneys for Defendants
 PFIZER INC, PHARMACIA
 CORPORATION, and G.D. SEARLE
 LLC

Gordon & Rees, LLP
 275 Battery Street, Suite 2000
 San Francisco, CA 94111